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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,679	02/25/2004	Nicholas J. Bate	1587	3609

27310 7590 02/13/2007

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EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	**PAPER NUMBER**
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,679	BATE ET AL.	
	Examiner	Art Unit	
	Cathy K. Worley	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *13-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S.Code not included in this action can be found in a prior Office action.

Election/Restriction

2. In the previous Office Action the examiner required restriction between product (group I) and process (group II) claims; and the Applicant elected the product of group I by telephone.

The Applicant is reminded of rejoinder practice; where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability

including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

It is noted that the withdrawn claims directed to methods have not been amended to depend from or to otherwise include the limitations of the instant product claims.

Obejctions and Rejections that are Withdrawn

3. The objections to the specification for a title and abstract that were not descriptive enough and for the use of trademarks are withdrawn in light of the Applicant's amendments to the specification.

4. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, is withdrawn in light of the Applicant's amendment of the claim.

5. The rejection of claim 1 under 35 U.S.C. 102(b) over Bonello et al. is withdrawn in light of the Applicant's amendment of the claim.

6. The rejection of claims 1-12 under 35 U.S.C. 102(b) over Chaudhary et al. is withdrawn in light of the Applicant's amendment of the claims.

Claim Objections

7. Claim 10 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

8. Claims 1-12 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record stated in the previous Office Action mailed on Sept. 26, 2006. The Applicant's arguments in the response received on Dec. 20, 2006 have been fully considered but were not found to be persuasive.

The amended claims encompass nucleic acids having at least 90% identity to SEQ ID NO:1 and nucleic acids that hybridize to SEQ ID NO:1 under specific stringency conditions.

The recitation of nucleic acids with only 90% identity allows for 10% of all bases to be changed. Ten percent of the 590 bp of SEQ ID NO:1 is 59 bases. This encompasses any combination of A, G, T, or C at 59 different positions, which includes 4^{59} molecules (3.3×10^{35}). The genus of molecules that hybridize under the specified conditions is also a very large genus of molecules; for example; using standard calculations for hybridization, a fragment of SEQ ID NO:1 with as few as 30 bases would hybridize to the nucleic acid of SEQ ID NO:1 under the specified conditions; and longer fragments with assorted random mismatches would also hybridize under the recited conditions. Therefore, the genus of molecules that is claimed in the instant encompasses multitudes of molecules. However, the applicants have only described one molecule, which is SEQ ID NO:1. This does not constitute a representative number.

The Applicant argues that the requirement for written description is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language (see paragraph bridging pages 11-12 of the response).

This is not persuasive, however, because one of skill in the art would have understood that the instant inventor was in possession of a nucleic acid comprising SEQ ID NO:1. One of skill in the art would not have any reason to believe that the instant inventor was in possession of the genus of molecules encompassed by the

instant claims, or even a representative number of molecules encompassed by the instant claims.

The Applicant further argues that the courts have held that if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, citing *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996) (see paragraph bridging pages 11-12 of the response).

This is not persuasive, because in the case of *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996), the inventor was in possession of 12 analogs of the claimed polypeptide (see second paragraph on page 1581 in the Background section). In the instant application, the inventor has only demonstrated possession of one of the molecules within the large genus encompassed by the claims. One molecule is not a representative number of the large genus encompassed by the instant claims.

The Applicant further argues that it would be well within the purview of one of skill in the art to make modification to SEQ ID NO:1 (see third paragraph on page 12 of the response), and that the Applicant has provided functional characteristics coupled with a known or disclosed correlation between function and structure (see paragraph bridging pages 12-13 of the response).

This is not persuasive, however, because the applicants have not provided any guidance about what structures are required for the promoter activity. The specification merely describes a bioinformatics approach that identified motifs that are conserved between the instant SEQ ID NO:1 and promoters from the prior art (see page 14), however, no experiments were performed to show that these motifs are sufficient for promoter activity. With no description of a structure/function relationship between certain subsequences or motifs and the promoter function, and with only one molecule described out of the multitudes of molecules included in the claimed genus, the written description requirements have not been met.

9. Claims 1-12 remain rejected under 35 U.S.C. 112, first paragraph, for scope of enablement, for the reasons of record stated in the previous Office Action mailed on Sept. 26, 2006. The Applicant's arguments in the response received on Dec. 20, 2006 have been fully considered but were not found to be persuasive.

The amended claims are broadly drawn to an isolated nucleic acid molecule comprising a sequence having at least 90% identity to SEQ ID NO:1 or hybridizing to SEQ ID NO:1 under specified conditions, and to expression cassettes, vectors, plant cells, seeds, and plants comprising said nucleic acid molecule.

The Applicant argues that the court has held that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples, in *In re*

Wright, 999 F. 2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993) (see 7th paragraph on page 13 of the response).

This is not persuasive, however, because in *In re Wright*, 999 F. 2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993) the court held that one working example was not sufficient to enable the broad scope of the invention: "In the present case, the PTO set forth a reasonable basis for finding that the scope of the appealed claims is not enabled by the general description and the single working example in the specification" (see page 1514, part B).

The Applicant further argues that the teaching of Kim et al. shows that evaluation of promoter function via mutation and expression analysis was, at the time of filing, routine and well within the skill of those in the art, and that the courts held that the enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation; citing *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 68 USPQ2d 1280 (Fed. Cir. 2003) (see paragraph bridging pages 13-14 of the response).

This is not persuasive, however, because in *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 68 USPQ2d 1280 (Fed. Cir. 2003), the court held that the claims were not enabled through their full scope because when a range is claimed there must be reasonable enablement of the scope of the range; and in the case of *AK Steel Corp. v. Sollac*, there was clearly an embodiment within the range that was not enabled (see page 1287).

The Applicant further argues that a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed, citing *Ex parte Jackson*, 217 USPQ 804, 817 (Bd. App. 1982) (see third paragraph on page 14 of the response).

This is not persuasive, however, because in the case of *Ex parte Jackson*, the court held that the invention was only enabled for those embodiments for which there had been a biological deposit (see page 809). Therefore, this decision does not support enablement across a large genus of molecules for which there has only been one molecule demonstrated to have the necessary activity.

In the instant case, the specification compares the sequence of SEQ ID NO:1 with other promoters that are known in the art, and the specification discloses that some of the conserved motifs are present in SEQ ID NO:1, while others are absent from SEQ ID NO:1 (see page 14). These elements are distributed throughout the 590 base-pair molecule of SEQ ID NO:1; at positions 135-139, 274-278, 552-556, 248-253, 447-452, 412-417, and 449-455 (see page 14).

The specification discloses *in situ* hybridization that demonstrated the tissue-specificity of the endogenous transcript from the maize INVINH1 gene (see Figure 1, page 39 lines 9-13 and page 40 lines 5-23). The specification also discloses several prophetic examples for the transformation of plants with the ESR-preferred promoter of the invention operably linked to a gene of interest (see pages 40-49).

The specification has not provided any guidance about which motifs or domains are sufficient for promoter activity. The prior art teaches that even minor alterations can alter promoter activity. Kim et al. (Plant Mol. Biol., 1994, Vol. 24, pages 105-117) teach that the deletions of just a few nucleotides can abolish promoter activity (page 109). The Applicant's disclosed analyses of conserved domains would suggest that there may be many different *cis*-elements necessary for the functionality of the instant promoter. In the absence of further guidance, one skilled in the art is left to randomly produce an endless number of substitutions and deletions of nucleotides from SEQ ID NO:1, which is undue experimentation.

10. Claims 1-30 are pending in the instant application. Claims 13-30 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-12 are rejected. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW